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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,604	05/16/2001	Brigitte Gicquel	03715.0062-01	2574

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,604

Applicant(s)

GICQUEL ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-147 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 75-147 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 75-147 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 75-86, 100, 116, 117 and 118, drawn to a vector, classified in class 435, subclass 320.1 and a recombinant mycobacterium, classified in class 435, subclass 253.1.
- II. Claims 87-88, drawn to a method of screening for nucleotide sequences, classified in class 435, subclass 6.
- III. Claims 89-92, drawn to a library, classified in class 436, subclass 536.
- IV. Claims 93-98, 101, 102, 103 and 107, drawn to a nucleotide, classified in class 536, subclass 23.1.
- V. Claims 99, 104-106 and 120, drawn to a polypeptide, classified in class 530, subclass 350.
- VI. Claims 108-115, drawn to primers and probes, classified in class 536, subclass 24.3.
- VII. Claims 119, 120 and 124, drawn to a method of preparing a polypeptide, classified in class 435, subclass 69.1.
- VIII. Claims 121-122, drawn to a hybrid polypeptide, classified in class 435, subclass 69.7.

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- IX. Claim 123, drawn to a polynucleotide encoding a hybrid polypeptide, classified in class 536, subclass 23.1.
- X. Claim 125, drawn to a method for *in vivo* detection of antibodies, classified in class 435, subclass 69.1.
- XI. Claims 126 and 127, drawn to a method for detection of an infection and kit for same, classified in class 435, subclass 6.
- XII. Claims 128 and 129, drawn to mono or polyclonal antibodies, classified in class 424, subclass 130.1.
- XIII. Claims 130 and 131, drawn to a method for the specific detection of the presence of an antigen and kit, classified in class 435, subclass 6.
- XIV. Claims 132-138, drawn to a method for the detection and rapid identification of mycobacterium, classified in class 435, subclass 6.
- XV. Claims 139 and 140, drawn to a kit, classified in class 435, subclass 6.
- XVI. Claim 141, drawn to an immunogenic composition, classified in class 530, subclass 387.1.
- XVII. Claims 142-144, drawn to a vaccine, classified in class 514, subclass 44.
- XVIII. Claims 145-146, drawn to a method of screening, classified in class 435, subclass 6.
- XIX. Claim 147, drawn to a molecule for inhibiting growth of a mycobacterium, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of each of Groups I, III, IV, V, VI, VII, IX, X, XIII, XVI, XVII, XVIII and XX are separate and distinct products from each other differing chemically, biologically, structurally and functionally and are capable of separate use. The products of one group is not required to produce the products of the other methods. Thus, each of the above inventions is separately patentable over the other. In view of the above explanation, in view of the separate status in the art attributed to the above inventions, and in view of the different field of search each invention would require, a serious search burden would be presented to the examiner. For example, the vector and host cell of Group I, the library of Group III, the nucleotide of Group IV, the primers of Group VI or the polynucleotide of Group IX is not required to produce the polypeptide of Group V, the hybrid polypeptide of Group VIII, the antibodies of Group XII, the composition of Group XVI or the inhibitor of Group XIX, which can be produced synthetically or isolated from cells. Moreover, the protein products of Groups V, VIII, XII, XVI or XIX are not required to produce the products of Groups I, III, IV, VI or IX, which can be replicated in vectors without the use of any one of the protein products claimed in the other groups. Therefore, the inventions of the two groups are capable of supporting separate patents.

Inventions of Group I and Groups III-IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The products of Group I are not used in the methods of Groups II, VIII, XI, XII, XIV, XV and XIX. The operation, function and effects of the products are completely different and distinct from the operation, function and effects of the methods of Groups II, VIII, XI, XII, XIV, XV and XIX which identify nucleic acids, produce polypeptides, detect antibodies *in vivo*, detect infection, detect antigens or

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identify mycobacterium. Moreover, Inventions of Groups II, VIII, XI, XII, XIV, XV and XIX are distinct methods from each other, having different starting material, different outcomes and different uses such that they are each separately patentable from each other and separately patentable from the products of the above groups. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

This application contains claims directed to patentably distinct species of the claimed invention which require further restriction of the present claims. The nucleotide sequences and amino acid sequences of the instant claims are subject to a restriction requirement. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant's claimed sequences comprise open reading frames. Absent evidence to the contrary, each such nucleotide sequence or amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, in most cases, only one (1) independent and distinct sequence will be examined in a single application without restriction. Therefore, upon election of a group for examination that recite multiple sequences, Applicant must also elect a sequence within that group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination

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purposes as indicated is proper. Additionally, the search required for each of the above groups is not required for the others.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

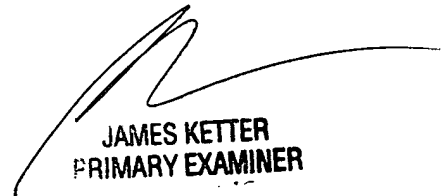
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
March 22, 2003


JAMES KETTER
PRIMARY EXAMINER